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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,395	07/24/2006	Yulin Ren	27211/04220	1395
24024 7590 04/15/2010 CALFEE HALTER & GRISWOLD, LLP 800 SUPERIOR AVENUE SUITE 1400 CLEVELAND, OH 44114				
EXAMINER KRISHNAN, GANAPATHY				
ART UNIT		PAPER NUMBER		
1623				
NOTIFICATION DATE		DELIVERY MODE		
04/15/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@calfee.com  
dcunin@calfee.com

# Office Action Summary

## Application No.

10/597,395

## Applicant(s)

REN ET AL.

## Examiner

Ganapathy Krishnan

## Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8, 12-19 and 23-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 12-19 and 23-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

The amendment filed 12/23/2009 has been received, entered and carefully considered.

The following information has been made of record in the instant amendment:

1. Claims 9-11 and 20-22 have been canceled.
2. Claims 1, 5, 8, 12-13, 16, 19, 23-24 and 27 have been amended.
3. Remarks drawn to rejections under 35 USC 112, first and second paragraphs.

The following have been overcome:

4. The objection to the Specification has been overcome by filing the Abstract on a separate sheet of paper.
5. The rejection of Claims 1-25 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for separation of  $\alpha$ -penta-O-galloyl-D-glucose and the  $\beta$ -anomers from a mixture containing 50% or more of the single anomer, does not reasonably provide enablement for the separation of the anomers from a mixture containing the  $\alpha$ -,  $\beta$ - and analogs of PGG, does not provide enablement for separation of  $\alpha$ -,  $\beta$ - and analogs of PGG in which the ring oxygen is substituted by C, N or S and does not provide enablement for separation of  $\alpha$ -,  $\beta$ - and analogs of PGG in which glucose is substituted by another hexose, pentose or tetrose, has been overcome by amendment cancellation of claims 9-11 and 20-22. The claims as amended are now drawn to separation of the alpha and beta anomers of PGG.
6. The rejection of Claims 1-29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been overcome by amendments. The term analogue has

been deleted from the instant claims and replacement of the term elevated by a value for the temperature.

Claims 1-8, 12-19 and 23-29 are pending in the case.

The following new art rejection is made of record.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8, 12-19 and 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khanbabaee et al (Tetrahedron, 1997, 53(1), 10725-32) in view of Experimental Organic Reactions (1957, 18, pages 504-505, English Translation).

Khanbabaee et al teach the preparation of pentagalloyl glucopyranose via the reaction of a mixture of alpha and beta-glucopyranose with gallic acid to afford a mixture of beta and alpha benzoylated anomers. The benzoylated anomers were separated by column chromatography and debenzoylated to give the pentagalloyl product (page 10727, Scheme 3 and the description above it). Khanbabaee et al do not teach the said separation of the alpha anomer from the beta anomer by dissolving the mixture in water or acetone and allowing the filtered solution to stand until crystals form, as instantly claimed. But his teaching shows that the alpha and beta anomers of the galloyl derivative can be separated from a mixture.

According to Experimental Organic Reactions (English translation of section 3.2) resolution of racemic modification (separation of anomers/optical isomers) can occur via recrystallization. Examples wherein water/methanol or acetone is used to separate racemates are disclosed (Translation, page 1, second paragraph). This means that alpha and beta anomers can be separated via crystallization.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to separate the alpha and beta anomers of penta-O-galloyl-D-glucose from a mixture of the alpha and beta anomers via the method as instantly claimed since analogous separations via crystallization using water/methanol or acetone as solvents have been disclosed in the prior

art. The prior art also shows that it is possible to separate alpha and beta anomers of the penta galloyl derivative of glucose.

One of ordinary skill in the art would be motivated to use the method as instantly claimed since crystallization is a well known technique for separation of compounds from a mixture and as disclosed in the art readily available solvents like water and acetone have been successfully used for such separations. One of ordinary skill in the art would expect the separation of the alpha and beta galloyl derivatives of glucose to also take place with a reasonable expectation of success.

MPEP 2141 states, "The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusatory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." KSR, 550 U.S. at 82 USPQ2d at 1396.

Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) " Obvious to try " choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor

may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention."

Rationales (A), (C) and (E) are applicable in this case. The prior art teaches the use of water and acetone for separating components from a mixture via crystallization using these two solvents, which are also used in the instant method. In the instant case separation of the alpha and beta anomers by choosing a known method (crystallization) and choosing a solvent for crystallization from a finite number of choices disclosed in the prior art with a reasonable expectation of success, according to KSR renders the instant claims obvious.

### **Conclusion**

Claims 1-8, 12-19 and 23-29 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ganapathy Krishnan/

Examiner, Art Unit 1623

/Traviss C McIntosh III/  
Primary Examiner, Art Unit 1623  
April 12, 2010